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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/722,357 | 11/24/2003 | Michela Gallagher | JHUC-0008-101 | 4705 |

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PATENT DOCKETING 39/361
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NEW YORK, NY 10036-8704

| EXAMINER | |
|---|---|
| RAE, CHARLESWORTH E | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1611 | |

| MAIL DATE | DELIVERY MODE |
|---|---|
| 11/07/2008 | PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/722,357 | GALLAGHER ET AL. | |
| | Examiner | Art Unit | |
| | CHARLESWORTH RAE | 1611 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *24 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *44 and 53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44 and 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/06/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114, filed 07/24/08.

### Status of the claims

Claims 44, and 53 are currently pending in this application.

### Claim amendment

Applicant's claim amendment, filed 07/24/08, is acknowledged and made of record. Applicant's statement that the amendment is fully supported by the specification (e.g. para 0003, 0022, 0057, and 0125) as published (US Patent App. No. 2004/0191803) and does not encompass new matter is also acknowledged.

### Response to applicant's arguments/remarks

Rejection under 102(e)

This rejection is withdrawn in view of applicant's claim amendment and persuasive arguments (see applicant's Response, received 07/24/08, pages 5-8).

Rejection under 112, 2nd paragraph

This rejection is withdrawn in view of the amendment.

## NEW REJECTION

### Claim rejections – 35 USC 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 44 and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohuchida et al. (U.S. Patent No. 7,176,240), in view Sramek et al. (Sramek et al. The status of ongoing trials for mild cognitive impairment. Opin. Invest. Drugs. 2001;10(4):741-752).

Claim 44 recites "a method of treating Mild Cognitive Impairment (MCI) in a mammal, comprising the step of administering a pharmaceutical composition comprising a therapeutically effective amount of a compound" having the below formula:

II

to said mammal, wherein:

X is -OH, -O-alkali metal, $-NH_2$, or $-SH$; and

R is $-CH[(CH_2)_2CH_3]_2$.

Claim 53 recites "wherein said mammal is human."

Ohuchida et al. teach a method for treating neurodegenerative diseases (e.g. Alzheimer's disease, Amyotropic lateral sclerosis, progressive supra nuclear palsy, olive-pontyo-cerebellar atrophy, multiple sclerosis, and AIDS dementia) comprising administering an effective amount of a pentanoic acid derivatives (e.g. valproic acid = applicant's elected compound species) in amounts useful for improvement of cerebral function in animals, including human beings (see abstract; col. 1, line 16 to col. 4, line 67; and col. 27, line 64 to col. 28, line 10). In particular, Ohuchida et al. (US Patent 7,176,240 B2) teach that pentanoic acid derivatives are potentially useful in improving the GABA receptor responses (column 3, lines 53-61; columns 7-8). Ohuchida et al. also teach that these pentanoic acid derivatives and non-toxic salts and acid addition salts thereof are useful for prevention and/or treatment for neurodegenerative disease (Alzheimer's disease etc.) and neuronal dysfunction by stroke or traumatic injury

(multiple sclerosis etc.) (abstract). Ohuchida et al. disclose that abnormalities in the astrocyte may be the determinant factors in inducing various brain-related diseases (column 2, lines 17-19).

Although Ohuchida et al. provide a general teaching of neurodegenerative diseases, this reference does not teach MCI.

Sramek et al. is added to show that drugs that are employed to treat Alzheimer's disease (i.e. neurodegenerative diseases) are also likely to be used in the treatment of MCI. Sramek et al. teach that as much as 38% of the elderly population meet the criteria for MCI and that up to 15% of these patients (i.e. MCI patients) convert to Alzheimer's disease (AD) annually (abstract). Sramek et al. teach that since there is a high conversion rate from MCI to AD, it is likely that many patients with MCI have underlying neuropathology of AD, and that treatment strategies developed for treating AD have been the first employed to treat patients with MCI (abstract).

It would have been obvious to a person of skill in the art at the time the invention was made to treat a patient with MCI as taught by Sramek et al. with a pentanoic acid derivative (e.g. valproic acid) as taught by Ouchida et al. to improve cerebral function. One would have been motivated to treat MCI with a pentanoic acid derivative (e.g. valproic acid) because Sramek et al. suggest that drugs used to treat AD may be used to treat MCI and Ouchida et al. teach pentanoic acid derivative drugs (e.g. valproic acid) for use in the treatment of AD. One would have expected to successfully treat MCI with a pentanoic acid derivative (e.g. valproic acid) because Ouchida et al. provides a

general teaching for treating neurodegenerative diseases comprising administering an effective amount of a composition comprising a pentanoic acid derivative (e.g. valproic acid) and MCI is a neurodegenerative disease.

Thus, a person of skill in the art at the time the invention was made would have found it obvious to create the instant claimed invention with reasonable predictability.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau, can be reached at 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http:pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the

automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

20 October 2008
/C. R./
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/

Supervisory Patent Examiner, Art Unit 1611